



CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE
BOARD OF PHARMACY

TELEPHONE: (302) 744-4500
FAX: (302) 739-2711
WEBSITE: DPR.DELAWARE.GOV
EMAIL: customerservice.dpr@state.de.us

PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, April 18, 2018 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	May 16, 2018

MEMBERS PRESENT

Hooshang Shanehsaz, R.Ph., Professional Member, President
Tejal Patel, PharmD, MBA, Professional Member, Vice President
Bonnie Wallner, R.Ph., Professional Member
Susan Esposito, R.Ph., Professional Member
Nicholas Juliano, PharmD, Professional Member
Gayle MacAfee, Public Member

MEMBERS ABSENT

Jay Galloway, Public Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Geoffrey N. Christ, R.Ph., J.D., Executive Director Board of Pharmacy
Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Jennifer Morris
Carolee Fullman
Tim Brown
Ravi Pappu, R.Ph.
Jagadishkumar Rabadia
Frank Tiano
Craig Hughes
Johnson Manoharan
Vincent Madalive
Suzanne Raab-Long
Matthew Forman
Jen Raubley
Daniel Hines
Rajiv Rao
John Giacobello
Sarah Wu
Desta Kamala
Layme Govens
Donna Ellis

Richard Kwabeng
Elizabeth Lewis
Lisa Flahartey
Martin Blood
Kim Robbins
Kevin Musto

CALL TO ORDER

Mr. Shanehsaz called the meeting to order at 9:32 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Patel and seconded by Ms. Wallner to approve the February 21, 2018 meeting minutes with corrections. The motion carried.

UNFINISHED BUSINESS

Hearing Request to Lift Suspension @9:30 am – Jennifer Morris –

The hearing for Jennifer Morris started at 9:36 a.m. Ms. Kelly stated the purpose of the hearing. The Board members introduced themselves. The following documents were marked as exhibits and entered into evidence: Final Order of Suspension, and documentation regarding Jennifer Morris' participation in substance abuse program. Jennifer Morris was advised of her right to legal representation and she confirmed that she was aware and wanted to proceed without legal representation. Jennifer Morris was sworn and provided testimony. The Board questioned Jennifer Morris. The Board went into deliberations at 9:55 a.m. A motion to approve with stipulation lift the suspension and impose probation was made by Ms. Esposito and seconded by Mr. Juliano. By unanimous vote, the motion carried. The hearing concluded at 10:05 a.m.

Review and Signing of Final Order for Proposed Rules and Regulations Changes

Ms. Kelly provided the Board a copy of the final order. The order was passed to the members of the Board for their signature.

Statutory and Regulatory Discussion

None

Re-review of Tabled Application(s)

Zevacor Pharma, Inc. (NJ) - a motion was made by Ms. Patel and seconded by Ms. Esposito to approve the application. The motion unanimously carried.

Glen Rock Medical Pharmacy (NJ) - a motion was made by Ms. Esposito and seconded by Ms. Wallner to approve the application. The motion unanimously carried.

BDI Pharma, LLC. (SC) - a motion was made by Ms. Esposito and seconded by Ms. Wallner to approve the application. The motion unanimously carried.

BDI Pharma, LLC. (TX) - a motion was made by Ms. Patel and seconded by Ms. MacAfee to approve the application. The motion unanimously carried.

PRESIDENT'S REPORT

Mr. Shanehsaz provided the following report:

- Attended Substance Abuse and Mental Health Services Administration (SAMHSA) Region III Naloxone Coordination Group Monthly Call
- To increase access to health professionals in under-served areas met with representatives from Delaware Pharmacist Society and Medical Society of Delaware discussing Collaborative Practice Agreement.
- SB157 AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO EXPEDITED PARTNER THERAPY. Mr. Shanehsaz provided the Board a summary of the bill for review. A motion

was made by Ms. Esposito and seconded by Ms. Wallner to support the bill with additional language to add pharmacist to the listing of healthcare professionals. Ms. Kelly will prepare the letter of support.

Executive Director's Report

Mr. Christ provided the following report:

Mr. Christ had a conversation with Devashree Brittingham, Director of the Board of Medical Licensure and Discipline (BOMLD) regarding the proposed regulation change requiring diagnosis to be included on the prescription. Ms. Brittingham stated that the BOMLD is opposed to the addition of a diagnosis to the prescription but, is open to further discussion with the Board of Pharmacy.

Mr. Christ and Eileen Kelly are continuing their work revising language corrections in current statute and regulation.

Mr. Christ and Mr. Slavoski attended the Jurisprudence examination question writing conference held at the National Boards of Pharmacy Association (NABP) offices in March.

Mr. Christ has finalized the electronic retail pharmacy inspection report. The report is electronic and a fillable .pdf file. He will be creating a similar electronic form for hospital inspections in the near future.

Mr. Christ has revised the system for communicating the "Alerts" that are sent to pharmacies in the state.

Mr. Christ has completed follow up inspections in Sussex County, De. He will continue to focus on Sussex County in the future to assist the Pharmacist Compliance Officer in providing coverage for that county.

Mr. Christ is continuing to grow relationships with regulatory affairs personnel of pharmacies located within Delaware. He will be providing a presentation to the Delaware Academy of Physician Assistants later in the month. He will also be attending NABP conference in Denver Colorado in May.

A motion to move ahead in the agenda to the Prescription Monitoring Program (PMP) Report was made by Ms. Wallner and seconded by Ms. Patel. The motion carried.

Mr. Christ provided the following PMP report on behalf of Mr. Slavoski:

Rhode Island and Massachusetts have been added to the PMP data sharing interconnect. This brings the total states sharing to 17. The data Analyst position has been filled. Data cleanup process has been started.

An email was sent to 3800 unregistered controlled substance registration holders notifying them of their statutory requirement to register with the PMP. 800 responded by registering in a 48 hour period.

PMP prescriber report cards have been created and sent to prescribers of controlled substances.

NEW BUSINESS

Mr. Shanehsaz read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0005208 Amanda Misiewicz Runyon

A1-0005209 Rabia Maryam Stevenson

A1-0005210 Mary Ann Rogers

A1-0005211 Alison M. Ney

A1-0005212 William J. Libera

A1-0005213 Amer Ahmed

A1-0005214 Megan A. Cox

A1-0005215 Ellen H Yankellow

A1-0005216 Mriam Bahy Raghieb Bakheit

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern:

A7-0002477 Bridget M. Zambito

A7-0002478 Rene Dohnjenka Effoe

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0002151 Lifeline Rx LLC

A9-0002152 MXP Pharmacy

A9-0002153 HPC, LLC

A9-0002154 AIDS Healthcare Foundation dba AHF Pharmacy

A9-0002155 The John Hopkins Hospital dba John Hopkins, Outpatient Pharmacy at Holabird

A9-0002156 K&C Pharmacy Depot, LLC

A9-0002157 Coastline Pharmacy LLC

A9-0002158 The Woodlands Apothecary

A9-0002159 Lynchburg Drug Store

A9-0002160 Soleo Health Inc

A9-0002161 CRE8 Pharmacy Group, LLC

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0000559 Caremark LLC d/b/a CVS Specialty

A4-0002491 Fresenius Kabi, LLC

A4-0002492 Empire Rx, Inc.

A4-0002493 Denver Solutions, LLC dba Leiters Health Pharmacy

A4-0002494 Right Way Medical, LLC

A4-0002495 Greenhill Trading Inc.

A4-0002496 Advanced Pharmaceuticals, LLC

A4-0002498 Masters Drug Company, Inc.

A4-0002499 Masters Drug Company, Inc.

A4-0002500 Masters Drug Company, Inc.

A4-0002501 Merial, Inc.

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Distributor Licensure Approval Ratifications

A2-0000151 Home MediService, LLC

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Medical Gas Distributor applications. The motion unanimously carried.

Manufacturer

None

Retail Pharmacy Licensure Approval Ratification

None

Non-Retail Pharmacy Licensure Approval Ratification

None

Outsourcing Facility

AD-0000052 Denver Solutions, LLC dba Leiters Health

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Outsourcing Facility applications. The motion unanimously carried.

Board Review of Facility Applications

Katy Pharmacy (TX) - a motion was made by Ms. Esposito and seconded by Ms. Wallner to approve the application. The motion unanimously carried.

Board Review of Pharmacist Applications

None

Review of Hearing Officer Recommendation

John Giacobello – Ms. Kelly summarized the hearing officer recommendation for the Board. Ms. Esposito recused herself from the proceedings. Mr. Giacobello was present and addressed the Board. The Board engaged Mr. Giacobello in discussion regarding the allegations in the recommendation and his resolution of those allegations. The Board agreed with the recommended disciplinary action, but took exception to and amended the following; the probationary period increased to 5 years instead of 3 and Mr. Giacobello will have 30 days to enroll in the Delaware Professionals' Health Monitoring Program (DPHMP). Also, during his period of probation, Mr. Giacobello cannot work as a pharmacist-in-charge and he must be supervised at all times by a licensed pharmacist.

A motion was made by Ms. Wallner and seconded by Mr. Juliano to accept the hearing officer recommendation with the changes stated above. The motion carried.

Ms. Kelly will prepare the final order for signature during the May 2018 meeting.

Continuing Education Review

David Dryden NASCSA Conference October 17th through 20th, 2017 – a motion was made by Ms. Esposito and seconded by Ms. Patel to approve 11.25 continuing credits. The motion carried

Pharmacist and Pharmacy - Discussion/Action Items

None

COMMITTEE REPORTS

Legislative – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz, Bonnie Wallner and Gayle MacAfee

Ms. Patel reported that continued work on reviewing and updating the current statute is ongoing.

Continuing Education – Bonnie Wallner, Tejal Patel:

Ms. Wallner reported that review of criteria for ACPE or Non ACPE continuing education is being discussed.

Consumer Affairs – Jay Galloway, Gayle MacAfee

No Report

Professional Liaisons – Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

Ms. Kimberly Robbins, Executive Director, Delaware Pharmacist Society (DPS) - reported that the DPS annual convention is being held on May 7th through the 9th in Newark, De. Mr. James Kaminski will be honored with the Lifetime Achievement Award. Also, there is a drug take back event on April 28, 2018.

Controlled Substance Liaisons – Tejal Patel, Hooshang Shanehsaz:

No Report

INSPECTION REPORT - Michelle McCreary

Ms. McCreary reported ongoing pharmacy inspections and Pharmacist-in-Charge compliance inspections were completed throughout March and April. Ms. McCreary has the following concerns as a result of those inspections:

- Many stores currently do not have designated PICs as required by regulation
- PIC Interviews with the Board are not being completed or completed in a timely manner
- PIC are not familiar with the required inventory upon taking the PIC assignment or ending their PIC assignment within 30 days.
- Annual Self Inspections that are required to be completed in February are not completed.

Ms. McCreary also completed 5 closing inspections which resulted in the following concerns:

- Closing Procedures are not being adhered to or completed
- DEA 222 forms are not completed

Ms. McCreary reminded the Board of the National drug take back event scheduled for April 28, 2018 from 10am to 2pm.

PMP REPORT – Jason Slavoski

Mr. Christ provided this report earlier in the agenda.

Pharmacist-In-Charge Interviews

A motion to add the following to the agenda was made by Mr. Shanehsaz and seconded by Ms. Patel. The motion carried.

PIC – Richard Kwabeng, Walgreens Foxrun Wilmington, DE

PIC – Craig Hughes, Wal-Mart, Dover, DE

Consultant Pharmacist – Ravi Pappu, Cadia - New Castle Pharmacy

Ms. Wallner conducted the pharmacist-in-charge and consultant pharmacist interviews. She expressed that PIC's to review regulation 3.0 and for consultant pharmacists to review regulation 11 they would be held accountable for these responsibilities.

PIC - Jagadishkumar N Rabadia, Walgreens Wilmington, DE

PIC - Sarah Wu, Walgreens, Wilmington, DE

PIC - Matthew Forman, CVS #10238 Claymont, DE

PIC - Desta Kamala - Walgreens Dover, DE

PIC - Rajiv Rao, Walgreens #11011 Maryland Ave Wilmington, DE

PIC - Johnson Manoharan, Walgreens #11025 Kennett Pike Wilmington, DE

PIC - Martin Blood, Beebe Healthcare, Tunnel Cancer Center, Rehoboth Beach, DE.

Physician Assisant Advisory Committee

Mr. Shanehsaz stated he's attended 2 council meetings.

BOARD CORRESPONDENCE

Mr. Shanehsaz reviewed the following correspondence with the Board:

Accreditation Commission for Health Care (ACHC)

NABP, State Oversight of Drug Compounding

OTHER BUSINESS BEFORE THE BOARD

Ms. Esposito asked Ms. Robbins if she would consider remaining on the legislative committee in light of her recent resignation from the Board. The Board agreed they would like for her to continue to support the committee. Ms. Robbins graciously agreed.

PUBLIC COMMENT

Ms. Robbins Executive Director, DPS stated she is currently working with the Medical Society regarding collaborative care.

Ms. Hamilton wanted to call to the Boards' attention to 2 provisions in the Expedited Partner bill regarding pharmacist liability, labeling and confidentiality.

Mr. Musto stated that the NARCAN training for the individual can be located at www.helpisherede.gov . Pharmacies can verify the training. Pharmacies complete a form and send to Public Health once NARCAN is dispensed. Also a Golf tournament is scheduled for September 21, 2018 to assist with DPS/DPEC scholarships that are available at WWW.DPECNET.ORG .

NEXT SCHEDULED MEETING

The next meeting is scheduled for May 16, 2018 at 9:30 a.m., 2nd Floor Conference Room.

ADJOURNMENT

There being no other business before the Board, a motion to adjourn the meeting was made by Ms. Esposito and seconded by Ms. Patel at 12:41 pm. The motion unanimously carried.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mast". The signature is written in a cursive, flowing style.

Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy